IN THE SPECIFICATION

Please add the following paragraph at page 1, line 3 of the specification:

Priority Information

This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Serial No. 60/159,589, filed October 18, 1999.

Please amend the specification by replacing the paragraph on page 4, lines 1 through 9, with the following amended paragraph:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ)(www-ddbj.nig.ac.jp/);~~http://www.ddbj.nig.ac.jp/);~~ Genebank (www-ncbi.nlm.nih.gov/web/Genbank/Index.html);~~http://www.ncbi.nlm.nih.gov/web/Genbank/Index.html);~~ and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) (www-ebi.ac.uk/ebi_docs/embl_db.html~~http://www.ebi.ac.uk/ebi_docs/embl_db.html~~). A number of different search algorithms have been developed, one example of which [[are]]is the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequences queries (BLASTIN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology, 12:* 76-80 (1994); Birren, *et al., Genome Analysis*, *1*: 543-559 (1997)).

Please amend the specification by replacing the paragraph on page 20, line 27 through page 21, line 2, with the following amended paragraph:

A PCR probe is a nucleic acid molecule capable of initiating a polymerase activity while in a double-stranded structure with another nucleic acid. Various methods for determining the structure of PCR probes and PCR techniques exist in the art. Computer generated searches using programs such as Primer3 (www-genome.wi.mit.edu/cgi-bin/primer/primer3.cgi~~www-genome.wi.mit.edu/cgi-bin/primer/primer3.cgi~~), STSPipeline (www-genome.wi.mit.edu/cgi-bin/www-STS_Pipeline~~www-genome.wi.mit.edu/cgi-bin/www-STS_Pipeline~~), or GeneUp (Pesole *et al.*, *BioTechniques 25:* 112-123 (1998) the entirety of which is herein incorporated by reference), for example, can be used to identify potential PCR primers.

Please amend the specification by replacing the paragraph on page 39, lines 20 through 28, with the following amended paragraph:

A microarray-based method for high-throughput monitoring of gene expression may be utilized to measure expression response Schena *et al., Science 270:*467-470 (1995); www-cmgm.stanford.edu/pbrown/array.html;~~http://cmgm.stanford.edu/pbrown/array.html;~~ Shalon, Ph.D. Thesis, Stanford University (1996). This approach is based on using arrays of DNA targets (e.g. cDNA inserts, colonies, or polymerase chain reaction products) for hybridization to a "complex probe" prepared with RNA extracted from a given cell line or tissue. The probe may be produced by reverse transcription of mRNA or total RNA and labeled with radioactive or fluorescent labeling. The probe is complex in that it contains many different sequences in

various amounts, corresponding to the number of copies of the original mRNA species extracted from the sample.

IN THE CLAIMS

Please cancel non-elected claims 2-8 without prejudice to or disclaimer of the subject matter contained therein. Please **amend** claim 1. Please **add** new claims 9-15.

1. (Currently amended) A substantially purified nucleic acid molecule that encodes a lily protein or fragment thereof comprising a nucleic acid sequence ~~selected from the group consisting~~ of SEQ ID NO: 1 ~~through SEQ ID NO: 6041~~.

2-8. (Cancelled)

9. (New) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

10. (New) The substantially purified nucleic acid molecule according to claim 9, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

11. (New) A substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

12. (New) The substantially purified nucleic acid molecule of claim 11, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 95% and 100% sequence identity with a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

13. (New) The substantially purified nucleic acid molecule of claim 12, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% sequence identity with a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

14. (New) The substantially purified nucleic acid molecule of claim 13, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 99% and 100% sequence identity with a nucleic acid sequence of SEQ ID NO: 1 or complement thereof.

15. (New) The substantially purified nucleic acid molecule according to claim 11, wherein said nucleic acid molecule further comprises a region having a single nucleotide polymorphism.

Remarks

Non-elected claims 2-8 have been canceled without prejudice to or disclaimer of the subject matter contained therein. Claim 1 has been amended, and new claims 9-15 have been added. Following entry of the present amendment, Claims 1, and 9-15 are pending. Support for the foregoing amendments may be found throughout the specification, for example at page 13, lines 22 through 30, page 14, lines 7 through 24, in the original claims, and the sequence listing. The "http://" and underlining have been removed from all website addresses on pages 4, 20, and 39 of the specification. A paragraph has been added to indicate the priority information as indicated in the declarations filed on July 11, 2001. No new matter enters by these amendments.

I. Election/Restriction Requirement

Applicants acknowledge that Claims 2-8 remain withdrawn from further consideration by the Examiner as allegedly being drawn to a non-elected invention. Applicants acknowledge the finality of the restriction requirement but maintain their traversal. The Office Action states that the restriction remains proper because "conducting a search of ten or more sequences does place an undue burden on the Office...." Office Action at page 2. However, the Office has submitted no proof that a serious burden would be imposed by a search and examination of the entire application, including Claims 2-8 and at least ten nucleotide sequences as provided for in M.P.E.P. § 803.04. Furthermore, the Office does not contend that a search of more than a single nucleic acid sequence would pose an undue burden. Accordingly, for at least the foregoing reasons, Applicants maintain their traversal of the restriction requirement. Nonetheless, in order to facilitate prosecution, non-elected Claims 2-8 have been cancelled and Claim 1 has been amended to reflect the elected SEQ ID NO.

II. Objection to Claim 1

The Office objected to Claim 1 because Claim 1 allegedly encompassed non-elected sequences or inventions. Applicants respectfully submit that Claim 1 properly reads on the elected species. As such, the Office may consider Claim 1 to the extent that it reads on the

elected species. Nonetheless, in order to facilitate prosecution, Claim 1 has been amended. As such, reconsideration and withdrawal of this objection is respectfully requested.

III. Specification

a. Objection to the title of the invention

The Office alleged that the title is not descriptive and argued that a new title is required that is clearly indicative of the invention to which the claims are directed. Office Action at page 3. Applicants respectfully disagree. The present title, "Nucleic Acid Molecules and Other Molecules Associated with Plants," is indeed descriptive. After all, nucleic acid molecules are described throughout the specification, including in the examples, where nucleic acid molecules and other molecules associated with plants are described in detail. Moreover, Applicants respectfully submit that an inventor is free to act as her own lexicographer as long as he does not give any term a meaning that is repugnant to the art. *See In re Hill*, 161 F.2d 367, 73 U.S.P.Q. 482 (C.C.P.A. 1947). Accordingly, based on the foregoing, Applicants respectfully request that the Examiner withdraw the objection to Applicants' title.

b. Objection to embedded hyperlinks

The Examiner objected to the disclosure because it allegedly contained an embedded hyperlink and/or other form of browser-executable code. The "http://" has been removed from all website addresses on pages 4, 20, and 39 of the specification. The underlining has also been removed from all website addresses. As such, Applicants believe that the remaining website addresses do not contain embedded hyperlink or browser-executable code as specified in M.P.E.P. § 608.01. According to M.P.E.P. § 608.01, "examples of a hyperlink or browser-executable code are a URL placed between these symbols '< >' and 'http://' followed by a URL address." Applicants' disclosure, as amended, contains no such browser-executable code in the absence of embedded hyperlinks or browser-executable code. Accordingly, Applicants respectfully request that the Examiner withdraw the objection.

IV. Rejection Under 35 U.S.C. §101, Utility

Claim 1 was rejected under 35 U.S.C. § 101 for allegedly not being supported "by either specific and/or substantial utility or a well established utility." Office Action at page 6. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including isolating full-length cDNAs or genes, making antibodies, mapping genes, isolating homologous sequences, detecting gene expression, and as molecular markers. Office Action at page 6. However, despite this admission, the Office contends that none of these utilities constitutes a "specific" or "substantial" utility. Applicants respectfully disagree.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the claimed nucleic acid molecules are useful for determining the presence of polymorphisms, isolating promoter regions, obtaining nucleic acid homologues, and producing antibodies. *See, e.g.*, Specification at pages 24, *et seq.*, under the heading "Uses of the Agents of the Invention."

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. §101 is not compromised by its use as a tool in this manner. Likewise, many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed molecules possess the requisite utility under 35 U.S.C. §101.

In the Office Action, the Office provides no evidence challenging the disclosed utilities for the claimed nucleic acid molecules. Rather, the Office attempts to undermine the existing

utilities by stating that the asserted utilities "...are applicable to nucleic acid(s) and/or proteins in general..." Office Action at page 6. In short, the Office suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in patent law. *See Carl Zeiss Stiftung v. Renshaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...")

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club lacks legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires "reading into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. When used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequence and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants respectfully submit that the claimed nucleic acid sequence exhibits the requisite utility under 35 U.S.C. §101.

The Office states that "credibility has not been assessed." Office Action at page 7. However, credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603

(Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Office "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Office "must do more than question operability – [it] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A 1975) (emphasis in original); M.P.E.P. § 2107 ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). In the present case, the Office has not even attempted to meet this burden. Thus, the admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants respectfully submit that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Office has failed to raise any credible evidence challenging the asserted utilities. As such, the rejection of Claim 1 under 35 U.S.C. §101 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejection Under 35 U.S.C. §112, First Paragraph, Enablement

The Examiner has rejected claim 1 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action at page 7. Applicants respectfully disagree and assert that the rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VI. Rejection Under 35 U.S.C. §112, First Paragraph, Written Description

Claim 1 was rejected under 35 U.S.C. §112, first paragraph, written description because the specification allegedly "...provides insufficient written description to support the genus encompassed by the claims". Office Action at page 7. The Examiner argues that "[t]he skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides..." *Id.* Applicants respectfully disagree.

As the Examiner acknowledges at page 7 of the Office Action, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989).

A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification). Therefore, contrary to the Office's suggestion, Applicants' specification does indeed meet the burden imposed by *Vas-Cath*

Inc. v. Mahurkar, 19 U.S.P.Q.2d 1111, because it "clearly allow[s] persons of ordinary skill in the art to recognize that [Applicants] invented what is claimed."

According to the Examiner's argument, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. However, an adequate written description of a genus of nucleic acids may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.* Indeed, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Moreover, nucleic acid molecules falling within the scope of the present claims are readily identifiable – they comprise a nucleic acid molecule having a nucleic acid sequence of SEQ ID NO: 1. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the present specification. Thus, there is no deficiency in the written description support for Claim 1.

Based on the foregoing, Applicants respectfully submit that the rejection under 35 U.S.C. § 112, first paragraph, written description is improper. As such, Applicants request reconsideration and withdrawal of this rejection.

VII. Rejection Under 35 U.S.C. § 102

Claim 1 was rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Life Technologies Gibco BRL Products and Reference Guide. Office Action at page 8. Applicants respectfully disagree.

This reference does not anticipate claim 1. "It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985).

In the present application, Claim 1 is directed to a nucleic acid molecule which encodes a lily protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1. The Examiner alleges that Life Technologies anticipates Claim 1 because it discloses "random primers that are primarily hexanucleotides." Office Action at page 8. The Office Action further alleges that "[t]he population of hexamers is considered to have as an inherent property nucleic acid sequences that would encode at least two amino acids that are also encoded by SEQ ID NO: 1." *Id.*

The Examiner has applied an untenable interpretation of claim 1 to cover small fragments of the specifically claimed nucleic acid molecules, *i.e.*, fragments of six contiguous nucleotides, and on this basis concludes that Claim 1 is anticipated by the cited reference. A grammatically consistent interpretation of the claims at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "lily protein" directly preceding it. Further, because the phrase "or fragment thereof" appears before the transition phrase "comprising", it is clear that it does not refer to a fragment of SEQ ID NO: 1.

As such, claim 1 is directed to a nucleic acid molecule which encodes a lily protein or fragment thereof, *i.e.*, a fragment of a lily protein, comprising the nucleic acid sequence of SEQ ID NO: 1. Whatever else the Life Technologies reference cited by the Patent Office may teach or disclose, it does not teach or disclose SEQ ID NO: 1 in its entirety. Absent a teaching of each and every element of the claim, the reference cited by the Examiner does not anticipate pending Claim 1.

Based on the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102, are respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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